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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,807	03/24/2004	Qiong Cheng	CL2365USNA	8626

23906 7590 03/04/2005

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EXAMINER	
GEBREYESUS, KAGNEW H	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,807	CHENG ET AL.	
	Examiner	Art Unit	
	Kagnew H Gebreyesus	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4, 5, 7, 16, 18, 20, 21 in part and claims 10, drawn to DNA of SEQ ID NO: 1, encoding geranylgeranyl pyrophosphate synthase enzyme and a sequence with at least 70% identity to SEQ ID NO: 2, vectors, host cells and expression of protein classified in class 435, subclass 194.

II. Claims 4, 5, 7, 16, 18, 20, 21 in part, claims 11 are drawn to DNA of SEQ ID NO: 3, encoding zeaxanthin glucosy transferase enzyme and a sequence with at least 70% identity to SEQ ID NO: 4, classified in class 435, subclass 200.

III. Claims 4, 5, 7, 16, 18, 20, 21 in part, claims 12 are drawn to DNA of SEQ ID NO: 5, encoding a lycopene cyclase enzyme and a sequence with at least 70% identity to SEQ ID NO: 6, classified in class 536 subclass 23.2.

IV. Claims 4, 5, 7, 16, 18, 20, 21 in part, claims 13 are drawn to DNA of SEQ ID NO: 7, encoding a phytoene desaturase enzyme and a sequence with at least 81% identity to SEQ ID NO: 8, classified in class 536 subclass 23.2.

V. Claims 4, 5, 7, 16, 18, 20, 21 in part, claims 14 are drawn to DNA of SEQ ID NO: 9, encoding phytoene synthase enzyme and a sequence with at least 70% identity to SEQ ID NO: 10, classified in class 536 subclass 23.2.

VI. Claims 4, 5, 7, 16, 18, 20, 21 in part, claims 15, are drawn to DNA of SEQ ID NO: 11, encoding beta-carotene hydrolase enzyme and a sequence with at least 77% identity to SEQ ID NO: 12, classified in 536 subclass 23.2.

VII. Claims 1, 2, 6, 7, 17, 19, 21, 24, 20, 25, 26 in part, and claim 3 are drawn to DNA of SEQ ID NO: 18, comprising the crtE, idi, crtY, crtL, crtB and crtZ or a nucleic acid sequence with at least 95% identity to SEQ ID NO: 18, classified in 536 subclass 23.2.

VIII. Claims 8 and 9 in part are drawn to protein sequence of SEQ ID NO: 2, encoding geranylgeranyl pyrophosphate synthase enzyme classified in class 435, subclass 194.

IX. Claims 8 and 9 in part are drawn to protein sequence of SEQ ID NO: 4, encoding zeaxanthin glucosyl transferase enzyme classified in class 435, subclass 193.

X. Claims 8 and 9 in part are drawn to protein sequence of SEQ ID NO: 6, encoding lycopene cyclase enzyme classified in class 435, subclass 232.

XI. Claims 8 and 9 in part are drawn to protein sequence of SEQ ID NO: 8, encoding phytoene desaturase enzyme classified in class 435, subclass 189.

XII. Claims 8 and 9 in part are drawn to protein sequence of SEQ ID NO: 10, encoding phytoene synthase enzyme classified in class 435, subclass 193.

XIII. Claims 8 and 9 in part are drawn to protein sequence of SEQ ID NO: 12, encoding beta-carotene hydrolase enzyme classified in class 435, subclass 195.

XIV. Claims 23, 25-30, in part is drawn to a method of carotene production using a DNA of SEQ ID NO: 1, encoding geranylgeranyl pyrophosphate synthase enzyme classified in class 435, subclass 67.

XV. Claims 23, 25-30 in part are drawn to a method of carotenoid production using a DNA of SEQ ID NO: 3, encoding zeaxanthin glucosyltransferase enzyme classified in class 435, subclass 67.

XVI. Claims 23, 25-30 in part are drawn to a method of carotenoid production using a DNA of SEQ ID NO: 5, encoding a lycopene cyclase enzyme class 435, subclass 67.

XVII. Claims 23, 25-30 in part are drawn to a method of carotenoid production using a DNA of SEQ ID NO: 7, encoding a phytoene desaturase enzyme class 435, subclass 67.

XVIII. Claims 23, 25-30 in part are drawn to a method of carotenoid production using a DNA of SEQ ID NO: 9, encoding phytoene synthase enzyme class 435, subclass 67.

XIX. Claims 23, 25-30 in part is drawn to a method of carotenoid production using a DNA of SEQ ID NO: 11, encoding beta-carotene hydrolase enzyme class 435, subclass 67.

XX. Claims 22, 24-30 are drawn to a method of carotenoid production using a DNA of SEQ ID NO: 18, comprising the crtE, crtX, crtY, crtL, crtB and crtZ or a nucleic acid sequence class 435, subclass 67.

XXI. Claims 31-35 are drawn to a method of regulating carotenoid biosynthesis in an organism comprising over-expressing at least one carotenoids gene classified in 435 subclass 440.

XXII. Claims 31-35 are drawn to a method of regulating carotenoid biosynthesis in an organism comprising disrupting at least one carotenoid gene classified in class 435, subclass 440.

XXIII. Claim 36 is drawn to a *Pantoea agglomerans* strain DC404 comprising the 16s rDNA sequence as set forth in SEQ ID NO: 16 class 435, subclass 252.1.

Furthermore for groups XXI and XXII applicants must elect one or more carotenoids biosynthetic genes selected from:

(a) A geranylgeranyl pyrophosphate synthase gene
(b) A zeaxanthin glucosy transferase gene.
(c) A lycopene cyclase gene.
(d) A phytoene desaturase gene.
(e) A phytoene synthase gene.
(f) A beta-carotene hydrolase gene.

2. Inventions in Group I-VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions of group I-VI have separate utility such as encoding the enzymes necessary for the intermediate products in the biosynthetic pathway of carotenoids. See MPEP § 806.05(d). In addition geranylgeranyl pyrophosphate synthase gene produces geranygeranyl pyrophosphate that can be used as a precursor for the synthesis of phytohormones such as giberellines.

3. The invention of Group VII and the inventions of Groups I-VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for

patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because orthologs of these genes can be used. The subcombination has separate utility such as the production of distinct antibodies.

4. Inventions in Groups I-VII and VIII-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I-VII DNA and the protein of VIII-XIII each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA comprises a nucleic acid sequence and the protein of group II comprise unrelated amino acid sequences. The DNA has other utilities besides encoding the protein such as hybridization probe; the proteins can be made by another method such as isolation from natural sources or chemical synthesis.

5. Inventions in Group VIII-XIII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions of group VIII-XIII have separate utility such as the synthesis of distinct carotenoids or for the production of distinct antibodies. See MPEP § 806.05(d). In addition geranylgeranyl pyrophosphate synthase gene produces geranygeranyl pyrophosphate that can be used as a precursor for the synthesis of phytohormones such as gibberellins.

6. Inventions Groups VIII-XIII and Groups XIV -XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case chemical synthesis of the carotenoids can be used as opposed to a biological method of making these products.

7. Inventions in Groups XIV- XX are unrelated to the invention of Groups XXI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of carotenoid production and the method of regulating carotenoid biosynthesis, which also includes suppressing or disrupting the expression, cannot be used together comprise different steps and produce different effects.

8. Inventions in Groups VIII- XIII are unrelated to the invention of Group XXI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the enzymes/polypeptides of the carotenoid biosynthetic pathway and the method of regulating carotenoid biosynthesis cannot be used together.

9. Inventions Groups I-VII and the invention of Groups XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Groups I-VII can be used for hybridization.

10. Inventions Groups I-VII and inventions in Groups XIV-XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Groups I-VII can be used in hybridization methods.

11. Inventions in Groups I-XXI are unrelated to inventions in Groups XXII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the relationship between the polynucleotides of Groups I-VII encoding the carotenoid biosynthetic enzymes of groups VIII-XIII, the method of production of carotenoids and the method of regulating carotenoid biosynthesis and *Pectobacterium sp.* have not been shown.

12. Claims 29 and 30 are generic to a plurality of disclosed patentably distinct species comprising a variety of host cells and carotenoid compounds. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species host cell and a single carotenoid compound, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

1. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43).

3. Applicant is reminded that upon the cancellation of claims to a none elected invention the none elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

5. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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